

REMARKS

The claimed subject matter relates in part to assay devices for the detection of an analyte of interest. In some embodiments the devices comprise a housing; a first device region for receiving a fluid sample; and a second device region fluidly connected to said first device region and comprising one or more capture zones on a surface within said housing. Each capture zone comprises molecules of a first antibody or binding fragment thereof reactive with an analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of the analyte of interest with the first antibody. The devices also comprise a labeled reagent species dissolvably disposed on a surface within the housing that is in fluid communication with the second device region. This labeled reagent species comprises an enzyme conjugated to a second antibody or binding fragment thereof reactive with the analyte of interest, and form sandwich complexes with the analyte of interest and with the first antibody.

By this submission, claim 11 has been amended to clarify that the signal detected by the analyte sensor is mediated by the enzyme portion of the labeled reagent species. This amendment does not introduce new matter or necessitate a new search, and is offered solely to clarify the claimed subject matter for the benefit of the Examiner.

Applicant requests reconsideration of the claimed subject matter in view of the foregoing amendments and the following remarks.

1. 35 U.S.C. §102

Applicant respectfully traverses the rejection of claims 11-17 as allegedly being anticipated by U.S. Patent 5,637,469 issued to Wilding *et al.*

The present claims relate to devices that comprise, *inter alia*, a device region comprising one or more capture zones on a surface within a housing, where each capture zone comprises a first antibody or antibody fragment reactive with an analyte of interest, and at least one analyte sensor that detects an electrochemical signal related to reaction of the analyte of interest with the

first antibody. The signal is mediated by an enzyme conjugated to a second antibody or antibody fragment that forms sandwich complexes with the analyte and the first antibody.

The Examiner refers to column 2, lines 61-67, and column 3, lines 43-65, of the '469 patent as disclosing that a device having a surface with antibodies immobilized thereon. With regard to the detection of "flow impedance," "pressure," or "electrical conductivity," the Examiner refers to column 4, lines 21-30, of the '469 patent.

Applicants note, however, that "flow impedance," "pressure," and "electrical conductivity" are not electrochemical mechanisms. Electrochemical sensors detect an electron flow resulting from a chemical reaction taking place in an electrolyte. What is being detected in the '469 patent are "fluid flow properties" which change due to blockage of the flow path (e.g., changes in flow caused by particle agglutination or altered conductivity caused by the complete absence of fluid in a device region). '469 patent, column 4, lines 21-37. Moreover, in these embodiments of the '469 patent, there is no analyte sensor, electrochemical or otherwise, that detects a signal mediated by an enzyme conjugated to a second antibody in a sandwich complex, as in the '469 patent there is no enzyme mediating the changes in fluid flow properties to which the Examiner refers.

It should be noted that the '469 patent does not teach or suggest electrochemical detection of analytes within the type of mesoscale flow devices disclosed therein. The Office Action fails to set forth any reasoned basis as to how the '469 patent teaches all the recited claimed elements. The Examiner has not met the initial burden of establishing that the characteristic in question is present. *See, e.g.*, MPEP §2112. Because no *prima facie* case of anticipation has been established, Applicants respectfully request that the rejection be reconsidered and withdrawn.

2. 35 U.S.C. §103

Applicant respectfully traverses the rejection of claim 15 as allegedly being obvious over U.S. Patent 5,637,469 issued to Wilding *et al.* in view of U.S. Patent 5,726,026, also issued to Wilding *et al.*

Applicants respectfully submit that the secondary '026 patent is not prior art to the present patent application.

The primary '469 patent is a continuation of U.S. Patent Application 877,702, filed May 1, 1992. The secondary '026 patent is a continuation in part of this same U.S. Patent Application 877,702.

The subject matter in the '026 patent on which the Examiner relies in the rejection (amperometric or potentiometric detection of analytes in a mesoscale device) is not present in the disclosure filed May 1, 1992, and is not entitled to a filing date prior to 1994. More particularly, the effective priority date of the '026 patent is two years after the earliest priority document of the present application, which is U.S. patent application Ser. No. 07/887,526, issued as U.S. Pat. No. 5,458,852, filed on May 21, 1992. Applicants direct the Examiner's attention to the prior response filed in the present application, which provides a chart listing exemplary support for each element of the present claims in the '852 patent.

Should the Examiner continue to believe that the secondary '026 patent is citable as prior art in the present application, Applicants respectfully request that the Examiner point to a document establishing a priority date prior to May 21, 1992 for the subject matter on which the Examiner relies in the rejection.

Because no *prima facie* case of obviousness has been established, Applicants respectfully request that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 36671-716.303).

Respectfully submitted,

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By:



Ray Akhavan
Registration No. 58,120

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
Direct Dial: (202) 973-8832
Customer No. 21971